PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06

A1

(11) International Publication Number: WO 98/40035

(43) International Publication Date: 17 September 1998 (17.09.98)

(21) International Application Number: PCT/US98/05014

(22) International Filing Date: 13 March 1998 (13.03.98)

(30) Priority Data:
08/816,348 13 March 1997 (13.03.97) US

(71) Applicant: UNITED STATES SURGICAL CORPORATION [US/US]; 150 Glover Avenue, Norwalk, CT 06856 (US).

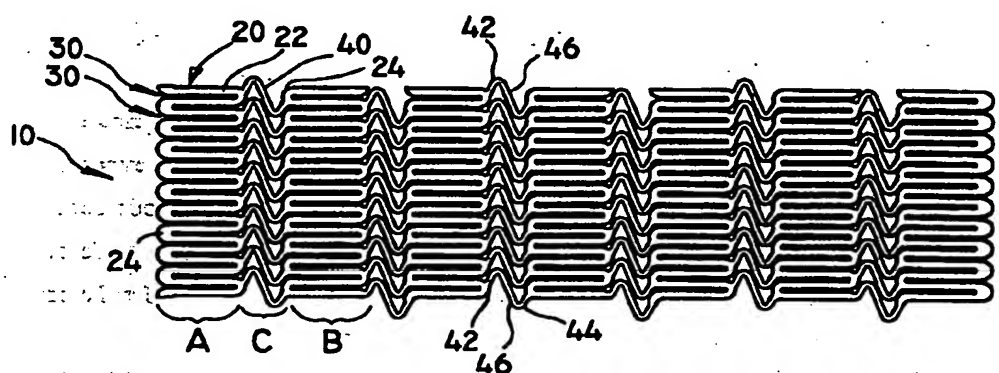
(72) Inventors: HESS, Robert, L.; 222 Wyndham Drive, Portula Valley, CA 94025 (US). MODESITT, Bruce; 120 Windgate Avenue, San Carlos, CA 94070 (US). ADZICH, Vaso; 10316 Scenic Boulevard, Cupertino, CA 95014 (US). JACKSON, Jerome; 1725 Fallen Leaf Lane, Los Altos, CA 94024 (US).

(74) Agents: GILBERT, Neil, Y. et al.; United States Surgical Corporation, Legal Dept., 150 Glover Avenue, Norwalk, CT 06856 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: FLEXIBLE TISSUE SUPPORTING DEVICE



(57) Abstract

A tissue supporting device (10) comprises first (A) and second (B) tubular sections interconnected by a bridging section (C). The tubular sections include a continuous strip (20) having aligned segments (22) and curved segments (30) interconnecting the aligned segments. The bridging section includes wavy strips (40), each of which includes a first (42) and second portion (44) inclined in a first direction and interconnected by a third portion (46) inclined in a second direction. The tissue supporting device is of a biocompatible material such as stainless steel, tantalum, gold or shape memory alloy such as a nickel–titanium alloy. The shape memory alloy can have a high transition temperature so that the tissue supporting device is permanently positioned to support the tissue of a tubular organ of a living body. The shape–memory allows the positioned tissue supporting device in the martensitic state and exhibits a strain on a plateau of a stress–strain curve of the shape–memory alloy when permanently positioned in the tubular organ.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

FLEXIBLE TISSUE SUPPORTING DEVICE

The present application is a continuation-in-part of pending U.S. Serial No. 08/637,330 filed April 23, 1996, a continuation of Serial No. 08/310,100 filed September 22, 1994, now U.S. Patent No. 5,545,210, the disclosures of which are hereby incorporated by reference.

Field of the Invention

The invention relates to tissue supporting devices (stents), preferably vascular stents for repairing blood vessels, and more particularly, to non-removable devices which will permanently support a dilated stenosis of a tubular organ (hollow viscus) such as a blood vessel.

Background of the Invention

In the past, permanent or biodegradable devices have been developed for implantation within a body passageway to maintain vascular patency. These devices are typically characterized by the ability of such an intravascular device to be enlarged radially after having been introduced percutaneously, to be transported transluminally, and to be positioned in a desired location. These devices are either expanded mechanically, such as by the expansion of a mandrel positioned inside the device, or are capable of releasing stored energy to expand themselves upon actuation within the body.

U.S. Patent Nos. 4,739,762, 4,776,337 and 4,733,665 disclose expandable and deformable intraluminal vascular grafts in the form of thin-walled tubular members which are expanded radially outwardly into contact with a body passageway, the members being plastically deformed beyond their elastic limit and the members being permanently fixed within the body. Suitable materials for the fabrication of these tubular-shaped members would include silver, tantalum, stainless steel, gold, titanium, or other suitable plastically deformable materials which may be permanently deformed. Permanent deformation is achieved when the material is subjected to a force which creates a strain greater than the elastic limit of the material which is utilized to make the tubular member. The open-mesh configuration of such devices is

soon encapsulated by body tissue and cannot be removed. The exceeding of the elastic limit of the material used in such devices is also believed to compromise the performance of the devices in situ.

Articulated prosthetic implants, grafts and stents are disclosed in U.S. Patent Nos. 3,657,744; 5,102,417; 5,104,404; 5,195,984; 5,449,373; and 5,545,210; and WO Publication No. 96/03092.

U.S. Patent No. 4,969,458 discloses a vascular stent formed from a wire component made of material, such as copper alloy, titanium, or gold, wherein the wound configuration unwinds upon expansion and becomes a permanent prosthesis stent, similar to prior art devices disclosed above, and is not removable.

U.S. Patent No. 4,969,890 discloses various configurations of shape-memory alloy members which have been previously radially compressed and which, upon positioning within the body and thermal activation, expand by themselves to become a permanent prosthesis within the body. In this regard, the reference teaches a device which operates in a similar fashion to the device disclosed in U.S. Patent No. 4,485,816. U.S. Patent No. 4,485,816 discloses a shape-memory alloy staple which, when heated, penetrates and cinches tissue together. Shape-memory alloy historically has been used to perform work in such a fashion wherein the component remains in a strong austenitic state after temperature activation. That is, above its transition temperature from martensite to austenite, and as the references above disclose, the shape-memory alloy either dilates an incompetent blood vessel or holds segments of tissue together. Neither of these devices is practically removable by a method which does not require surgery.

Shape-memory alloys possess the useful characteristic of being capable of changing physical dimensions upon heating above a first transition temperature, A_f, between a martensitic metallurgical state and a austenitic metallurgical state of the alloys. A shape-memory alloy member can be processed while in a high temperature austenitic phase to take on a first configuration. After cooling the shape-memory alloy member below a second transition temperature M_f between the austenitic and martensitic states without change of physical dimensions, the shape-memory alloy member can be mechanically deformed into a second configuration. The shape-

memory alloy member will remain in this second configuration until further heating to a temperature above A_f at which time the shape-memory alloy member will revert to its first configuration. A shape-memory alloy member can exert large forces on adjacent members during the transition from the second configuration to the first configuration. Numerous inventions have taken advantage of shape-memory alloy members capable of exerting this thermally activated force.

Shape-memory alloys have the further useful characteristic that, in the martensitic phase, the stress-strain curve exhibits a plateau indicating that a limited increase in strain can be achieved with minimal increase in stress. This martensitic stress-strain plateau usually defines the range of mechanical strain which can be recovered by the application of heat.

U.S. Patent No. 5,197,978, hereby incorporated by reference, discloses shape-memory alloy tissue supporting devices that are made to expand or shrink radially upon mechanical or thermal actuation, and, in particular, devices that are removable from the body.

It would be advantageous to have a flexible tissue supporting device of a generally tubular configuration which can be inserted into a body duct or cavity while in an unexpanded shape and then be expanded to provide permanent support for the tissue forming the duct or cavity, such that the device when expanded does not exert a radial load on the supported duct or cavity and where the device when expanded has sufficient crush resistance to provide support for the duct or cavity when the duct or cavity exerts a normal radial compressive load on the device as the result of major contractions of the tissue.

It would be further advantageous to have a flexible tissue supporting device, for simultaneous support of cavities of different sizes, in which larger expanded device sizes do not require substantially higher expansion pressures than smaller device sizes, so that the potential for dissection and/or tissue damage is minimized, and where further the device remains somewhat flexible to accommodate movement of soft tissue.

Summary of the Invention

The invention provides a flexible tissue supporting device comprising a first tubular section and a second tubular section interconnected by a bridging section. Each of the first and second tubular sections comprises a continuous strip having aligned segments and curved segments, each of the curved segments interconnecting adjacent ends of a pair of the aligned segments such that each of the aligned segments is connected to an adjacent one of the aligned segments by only one of the curved segments. The bridging section comprises a plurality of wavy strips, each of the wavy strips being connected between one of the curved segments of the first tubular section and one of the curved segments of the second tubular section.

The tissue supporting device can incorporate various features according to various embodiments of the invention. For instance, the aligned segments can be rectilinear and extend in an axial direction and the continuous strip can be uniform or nonuniform in cross section. Each of the wavy strips can include a first portion inclined in a first direction with respect to the aligned segments, a second portion inclined in the first direction, and a third portion inclined in a second direction, the third portion interconnecting the first and second portions and forming acute angles with the first and second portions. The wavy strips can interconnect all or only some of the curved segments at one end of the first tubular section with all or some of the curved segments at one end of the second tubular section.

According to one embodiment of the invention, the tissue supporting device is expandable from a first configuration to a second configuration wherein the second configuration has a pattern of identically shaped expanded openings. In the first configuration, the aligned segments can abut each other and in the second configuration the aligned segments can form a ring of wishbone-shaped segments. Further, in the first configuration, the wavy strips can abut each other and in the second configuration the wavy strips can be spread apart in a circumferential direction while maintaining substantially the shape they had in the first configuration.

The tissue supporting device can include any desired number of tubular and bridging sections. For instance, the tissue supporting device can include a third tubular section interconnected to the second tubular section by a second bridging

section, a fourth tubular section interconnected to the third tubular section by a third bridging section, a fifth tubular section interconnected to the fourth tubular section by a fourth bridging section, a sixth tubular section interconnected to the fifth tubular section by a fifth bridging section, a seventh tubular section interconnected to the sixth tubular section by a sixth bridging section, etc. The bridging sections can separate adjacent tubular sections in an axial direction and/or the bridging sections can be interleaved with the tubular sections. The tubular section and the wavy strips can comprise an etched, an electric discharge machined, or laser-cut tube or sheet of metal.

According to one embodiment of the invention, the curved segments can be enlarged curved segments which define a series of teardrop-shaped openings at opposite ends of the first and second tubular sections. Each of the enlarged curved segments can abut another one of the enlarged curved segments prior to expansion of the tissue supporting device.

The tissue supporting device can be of a biocompatible material such as stainless steel, nickel-titanium, shape memory alloy, tantalum, gold, or the like. For instance, the device can be comprised of a unitary piece of a shape-memory alloy which transforms from a martensitic metallurgical state to an austenitic metallurgical state when heated above a first transition temperature A_f and transforms from the austenitic state to the martensitic state when cooled below a second transition temperature M_f, the tissue supporting device being mechanically deformable without plastic deformation in a body passage of a living person from a first configuration while in the martensitic state to a second configuration in the martensitic state and the A_f temperature being sufficiently above a body temperature of the living person to prevent recovery of the tissue supporting device to the first configuration by heating the tissue supporting device above A_f without permanently damaging surrounding tissue of the living person, the tissue supporting device exhibiting a strain on a plateau of a stress-strain curve of the shape-memory alloy when permanently positioned in the body passage.

Brief Description of the Drawings

Fig. 1 shows a first embodiment of a flexible stent in accordance with the present invention;

Fig. 2 shows the stent of Fig. 1 in an expanded configuration;

Fig. 3 shows a shorter version of the stent shown in Fig. 1;

Fig. 4 shows a modification of the stent shown in Fig. 3;

Fig. 5 shows a portion of the stent shown in Fig. 1;

Fig. 6 shows a second embodiment of a flexible stent in accordance with the invention;

Fig. 7 shows a third embodiment of a flexible stent in accordance with the invention;

Fig. 8 shows a fourth embodiment of a flexible stent in accordance with the invention;

Fig. 9 shows a fifth embodiment of a flexible stent in accordance with the invention;

Fig. 10 shows a sixth embodiment of a flexible stent in accordance with the invention;

Fig. 11 shows a seventh embodiment of a flexible stent in accordance with the invention; and

Figs. 12 a-p show embodiments of wavy strips in accordance with the invention.

Detailed Description of the Invention

According to the invention, an axially flexible tissue supporting device is provided which can be inserted into a body passage, such as a blood vessel, duct or cavity, and used to support the tissue forming the duct or cavity. The tissue supporting device can be fabricated from biocompatible materials such as stainless steel, tantalum, gold, or the like, or from a shape memory alloy such as a binary Ni-Ti alloy or NiTi alloy having one or more additional elements added thereto. Other possibilities include shape memory alloys from the Cu-Al-Ni system. The tissue supporting device is of a generally tubular shape which can be inserted into a body

duct or cavity in an unexpanded shape and then be expanded at a desired position in the duct or cavity to form a permanent supporting structure for the tissue surrounding the expanded device.

According to a preferred embodiment, the tissue supporting device comprises a shape memory alloy which exhibits a stress-strain curve wherein an increase in strain can be achieved with a negligible increase in stress. Such shape memory alloys have martensitic and austenitic metallurgical states and a transition temperature therebetween. The shape-memory alloy used according to the invention is characterized by a stress/strain curve in the martensite state wherein a limited increase in strain can be achieved with minimal increase in stress.

The shape-memory property can be used in manufacturing the tissue supporting device. For instance, a tube of suitable shape-memory material such as Nitinol can be provided with a desired pattern of openings to create tubular sections interconnected by bridging sections. Then, the thus patterned tube can be mechanically expanded to a diameter the tissue supporting device will have when deployed in a tubular organ. The thus expanded tube can then be processed to provide a suitable surface finish or other feature. As an example, the internal surface finish can be provided by techniques such as honing and/or polishing. Subsequently, the processed tube can be shrunk by heating the tube to a temperature to transform the tube material into the austenitic state to thereby recover the original diameter of the tube, i.e. the tube's memorized configuration. Accordingly, the tissue supporting device is thus returned to a size which can be surgically delivered and subsequently mechanically expanded such as by a balloon catheter within a tubular organ of a patient. As an example, in the case where the tissue supporting device is a cardiovascular stent, the stent can be mechanically expanded in its martensitic condition to a diameter of 4 to 4.5 mm thus providing a greater surface area for surface finishing such as by polishing or honing to remove any sharp edges, etc., after which the stent can be shrunk to its original size by the heating the stent into its austenitic state. In this way, a better internal surface finish can be obtained on the stent due to its processing in the mechanically expanded state.

A tissue supporting device according to the invention can be made from a Ni-Ti alloy whose tensile strength in the martensitic state at human body temperature is 8 to 25 ksi. According to one embodiment of the invention, the transition temperature at which the alloy transforms from the martensitic to the austenitic state is preferably at a temperature of 70°C or higher. At such temperatures, known thermal recovery techniques for shrinking shape memory alloy tubular devices cannot be used to recover the tissue supporting device without causing permanent damage to surrounding tissue or blood due to thermal trauma which has been found to occur when tissue/blood is exposed to temperatures above 62°C.

A first embodiment of the invention is illustrated in Figs. 1 and 2 wherein the tissue supporting device 10 comprises a first tubular section A and a second tubular section B interconnected by a bridging section C. Figs. 1 and 3-11 show the device 10 as a flattened sheet of material which can be formed into a tubular shape such as by rolling the sheet into a tube and welding opposed edges of the sheet. However, the device 10 can be made directly from a tubular material, as explained earlier.

Each of the first and second tubular sections A, B comprises a continuous strip 20 having aligned segments 22 and curved segments 24 separated by slits 30, each of the curved segments 24 interconnecting adjacent ends of a pair of the aligned segments 22. The bridging section C comprises a plurality of wavy strips 40 connected between one of the curved segments 24 of the first tubular section A and one of the curved segments 24 of the second tubular section B. As shown in Fig. 1, each of the aligned segments 22 is connected to an adjacent one of the aligned segments 22 by only one of the curved segments 24. Although the aligned segments 22 are shown as rectilinear and extending in an axial direction, the aligned segments can have any desired configuration. Likewise, while the continuous strip 20 is shown as having a uniform cross section, the cross section of the aligned segments can be nonuniform in cross section.

As shown in Fig. 3, the tissue supporting device 10 can include four tubular sections A, B, D and E interconnected by three bridging sections C, F and G. However, the tissue supporting device can include any desired number of tubular sections and in the embodiment shown in Fig. 1, the tissue supporting device includes

seven short tubular sections interconnected by six bridging sections. A tissue supporting device comprised of such short tubular sections connected together by wavy strip bridging members 40 creates a tissue supporting device with the advantage of greater axial flexibility, i.e., the center axis of the tissue supporting device is easier to bend. This greater axial flexibility enables the device to be deployed through a more tortuous path. In addition, a tissue supporting device containing short tubular sections connected together by wavy strip bridging members 40 creates a device with the advantages of large perimeter side openings. The large perimeter side openings 50 provide access to side branching blood vessels while the bridging section minimizes spacing between the tubular sections to minimize prolapse of tissue between the tubular sections. The wavy strip bridging members 40 allow expansion of the tubular sections and formation of large perimeter side openings 50 while maintaining any desired axial spacing between the tubular sections. Further, as shown in Fig. 4, one or more of the wavy strips 40 can be omitted to create an opening 60 for access to side branches or accommodate a bifurcated vessel. For instance, the opening 60 can be used to allow a guide wire to pass axially through the tissue supporting device 10 and radially outwardly through the opening 60.

As shown in Fig. 1, each of the wavy strips 40 includes a first portion 42 inclined in a first direction with respect to the aligned segments 22, a second portion 44 inclined in the first direction, and a third portion 46 inclined in a second direction, the third portion 46 interconnecting the first and second portions 42, 44. In the embodiment shown in Fig. 1, the wavy strips 40 interconnect all of the curved segments 24 at one end of the first tubular section A with all of the curved segments 24 at one end of the second tubular section B. However, in the embodiment shown in Fig. 6, the wavy strips 48 connect only some of the curved segments 26 at one end of the first tubular section A with some of the curved segments 46 at one end of the second tubular section B.

In the embodiment shown in Fig. 6, some of the curved segments 26 are enlarged curved segments which define a series of teardrop-shaped openings 28 at opposite ends of the first and second tubular sections A, B. Each of the enlarged curved segments 26 abuts another one of the enlarged curved sections 26 in the

flattened state shown in Fig. 6. However, when the device is formed into a tubular shape, the enlarged curved segments 26 will either be abutting adjacent enlarged curved sections 26 or be located close thereto prior to expansion of the tissue supporting device.

Fig. 2 shows a perspective view of the expanded condition of the tissue supporting device 10 shown in Fig. 1. As shown in Fig. 2, in the expanded condition, the tissue supporting device includes a pattern of identically shaped open areas 50 and the aligned segments 22 form a ring of wishbone-shaped segments. Further, comparing Fig. 1 to Fig. 2, the tissue supporting device 10 is expandable from a first configuration in which the wavy strips 40 abut each other to a second configuration in which the wavy strips 40 spread apart in a circumferential direction and maintain their shape.

Fig. 7 shows an embodiment wherein the tissue supporting device 10 includes a continuous strip 70 formed by aligned segments 72,74,76,78, aligned segments 72,74 being parallel to each other and aligned segments 76,78 being parallel to each other but segments 72,74 not being parallel to segments 76,78. In addition the device 10 in Fig. 7 includes bridging members 80 which extend between a concave portion 82 of a curved segment of a first tubular section and a convex portion 84 of a curved segment of a second tubular section. Thus, the wavy strips 80 are interleaved between aligned segments 74,76. Additional wavy strips 86 having a pair of bends 87 extend between concave portions 88 of curved segments of two adjacent tubular sections with the wavy strips 86 interleaved between aligned segments 74,76. The device 10 shown in Fig. 8 includes wavy strips 80 extending between concave portions 82 and convex portions 84 of curved segments but is otherwise similar to the tissue supporting device shown in Fig. 7.

Fig. 9 shows an embodiment similar to Fig. 7 except that aligned segments 72a, 74a are generally parallel with aligned segments 76a, 78a whereas in Fig. 7 aligned segments 72, 74 are parallel with each other but not with aligned segments 76, 78. Fig. 10 shows an embodiment similar to Fig. 7 except that wavy strips 86a include a pair of bends 86b oriented in the same manner whereas the wavy strips 86 in Fig. 7 include bends 87 which are mirror images of each other. Fig. 11 shows an

embodiment wherein the tissue supporting device 10 includes tubular sections comprising a continuous strip formed by aligned segments 92, 94 and curved segments 96, the device further including wavy strips 98 connecting curved segments 96 of one tubular section to curved segments 96 of an adjacent tubular section. In the Fig. 11 embodiment, the wavy strips 98 are continuous and circumferentially spaced apart by expandable members such which, for example, can comprise a pair of adjacent aligned segments 92, 94 and attached pair of the curved segments 96. In the foregoing embodiments, an advantage of the interleaved bridging segments is that the tissue supporting device does not shorten axially upon expansion of the device.

Figs. 12 a-p show embodiments of wavy strips which can be used to form all or part of the bridging sections of the tissue supporting device. The wavy strips can have various configurations such as a sine wave shape as shown in Figs. 12 a-b having one or more repeating portions 102, a triangular wave shape as shown in Figs. 12 c-f having one or more repeating portions 104 wherein the triangles form acute angles or right angles, an acute biphasic triangular wave shape as shown in Figs. 12 g-h with one or more repeating portions 106, a low amplitude biphasic triangular wave shape as shown in Figs. 12 i-j with one or more repeating portions 108, a square wave shape as shown in Figs. 12 k-l with one or more repeating portions 110, a bilevel square wave shape as shown in Figs. 12 m-n with one or more repeating portions 112, or a ramp wave shape as shown in Figs. 12 o-p with one more repeating portions 114. However, alternative designs of the wavy strips can also be used, if desired.

The stent-like member 10 according to the claimed invention, when fabricated from a Ni-Ti shape-memory alloy, can be expanded in a blood vessel to a range of desired sizes by inflating a balloon catheter to a pressure of 4-10, preferably 6-8 atmospheres of pressure in the balloon catheter. When the stent is expanded, the slits 30 are enlarged into one or more groups of identically shaped openings arranged in a uniform pattern. For instance, the tissue supporting device can include first and second groups of openings, the first group of openings having a different shape than the second group of openings. In each of the embodiments, expansion of the individual sections can be performed separately to achieve different diameters. Due

to the expansion in the martensitic condition, sections expanded to larger sizes do not require substantially higher expansion pressures than sections expanded to smaller sizes provided that the tissue supporting device comprises sections made from the same generally tubular shape-memory alloy material. This embodiment offers the advantage of minimizing the potential for dissection and/or tissue damage.

The stent-like member 10 can be positioned at its application site in a low profile configuration with radial dimensions small enough to allow navigation of orifice and ducts leading to the site of application. The stent-like member 10 can be positioned by means of a balloon catheter device having a lumen portion, balloon portion, and guide portion with the stent-like member 10 surrounding the balloon portion. In a preferred embodiment, stent-like member 10 is mechanically crimped securely to the balloon portion prior to insertion of the balloon catheter device in a blood vessel.

In a preferred embodiment, the balloon portion is expanded, thus deforming stent-like member 10 radially outward against an inner wall of a blood vessel, and forming a supporting structure for the blood vessel. The expansion of the stent-like member according to the invention takes place in the elastic region of the stress-strain curve defined by the plateau in that curve. The deformed stent-like member 10 can comprise any of the specific shapes shown in Figs. 1-11 or any other suitable shape which can be mechanically deformed without permanently deforming the device. The stent is designed so that the strain in the expanded stent-like member 10 is controlled such as by the length of the tubular sections, bridging sections, and/or slits 30. Use of a shape memory NiTi alloy for the device is also advantageous since such material can exhibit anti-thrombotic properties.

Once the balloon catheter has been removed by collapsing the balloon portion, stent-like member 10 is left implanted to permanently support the blood vessel. The overall geometry of the stent-like member 10 ensures that the snapback at expansion is minimized and is proportional to the expanded size of the stent-like member 10. Since the implanted stent-like member exhibits a strain on a plateau of a stress-strain curve for the shape-memory alloy, the stent-like member can support the blood vessel at essentially constant stress. The expanded dimensions of the stent-like member 10

cannot be adjusted by the amount of force used to expand the device. Instead, the expanded diameter is controlled by the dimensions of the duct, cavity or, blood vessel, into which the stent-like member 10 is expanded. According to the invention, the shape memory alloy of the stent-like member 10 remains in the martensitic state when the stent-like member 10 is in service in a human body.

The duct supportive properties of an implanted member can be controlled by the alloy composition, processing conditions, wall thickness of shape-memory alloy forming the tube-like member, the length of tubular sections A, B, etc., and length of the bridging sections B, etc., and by the degree of expansion of the stent-like member 10. An implanted stent-like member 10 has sufficient crush resistance to provide support for a duct or cavity or blood vessel when such duct or cavity or blood vessel exerts a normal radial compressive load on the stent-like member 10 as the result of a major contraction of the duct or cavity or blood vessel. Preferably the stent-like member 10 can be sufficiently robust to support a coronary artery when major contractions are indicated. The implanted stent-like member 10 essentially does not exert a radial load on the duct or cavity or blood vessel it is supporting. The implanted stent-like member 10 allows for a small amount of radial recoverable deflection at low loads as the supported duct or cavity or blood vessel contracts. The low force needed to cause elastically recoverable deflection of stent-like members 10 in response to tissue duct contraction can advantageously minimize irritation to the duct wall when small contractions occur.

Although the invention has been described as useful in an angioplasty procedure, it is understood that the invention is not limited to such a procedure or the use of a stent-like member in a blood vessel. It should be apparent to one skilled in the art that the invention is useful in supporting body tissue in general as well as various blood vessels, e.g., in saphenous vein grafts, the vena cavae, the aorta, the renal artery, the iliac artery, the femoral artery, the popliteal artery, the carotid artery, the cranial arteries, pulmonary arteries, etc. The various embodiments of the invention are also useful with other tubular organs including but not limited to the prostate, biliary tract, the esophagus, the trachea, the Fallopian tubes, the vas deferens, the ureters, the tear ducts, the salivary ducts, etc.

The tissue supporting device according to the claimed invention can non-magnetic and corrosion resistant thus making it more compatible with specialized imaging methods involving electromagnetic waves, i.e., magnetic resonance imaging ("MRI"). Further, the tissue supporting device can include means for making the stent visible and radiopaque under conventional fluoroscopes when in the human body. For instance, the radial wall thickness of the tissue supporting device can be any suitable thickness such as 0.003 inches to 0.020 inches, thus making the stent visible by radiopaque techniques.

The stent according to the invention can provide benefits in preventing thrombogenic response. In particular, the stent geometry can be controlled to provide a planar cylindrical profile when expanded with minimal strut twisting and outwardly protruding stent strut terminations. That is, whereas the struts forming the mesh-like structure of stainless steel stents have a tendency to twist such that the edges thereof project radially outwardly when expanded by balloon inflation, the stent according to the invention can be expanded without such twisting of the various segments thereof. Further, compared to a stainless steel stent having the same configuration, the stent according to the invention can be expanded at much lower balloon expansion pressures. The lower expansion pressures used in accordance with the invention minimize barotrauma and the smooth outer cylindrical surface of the expanded stent in accordance with the invention provides non-thrombogenic properties.

The foregoing has described the principles, preferred embodiments and modes of operation of the present invention. However, the invention should not be construed as being limited to the particular embodiments discussed. Thus, the above-described embodiments should be regarded as illustrative rather than restrictive, and it should be appreciated that variations may be made in those embodiments by workers skilled in the art without departing from the scope of the present invention as defined by the following claims.

<u>WHAT IS CLAIMED IS</u>:

1. A flexible tissue supporting device comprising:

a first tubular section and a second tubular section interconnected by a bridging section;

each of the first and second tubular sections comprising a continuous strip having aligned segments and curved segments, each of the curved segments interconnecting adjacent ends of a pair of the aligned segments such that each of the aligned segments is connected to an adjacent one of the aligned segments by only one of the curved segments; and

the bridging section comprising a plurality of wavy strips, each of the wavy strips being connected between one of the curved segments of the first tubular section and one of the curved segments of the second tubular section.

2. The tissue supporting device of Claim 1, wherein each of the wavy strips comprises one or more repeating shapes.

3. The tissue supporting device of Claim 1, wherein each of the curved segments at one end of the first tubular section is connected to one of the wavy strips.

4. The tissue supporting device of Claim 1, wherein the aligned segments are rectilinear and extend in an axial direction.

5. The tissue supporting device of Claim 1, wherein the continuous strip is substantially uniform in cross section.

6. The tissue supporting device of Claim 1, wherein only every other one of the curved segments at one end of the first tubular section is connected to one of the wavy strips.

7. The tissue supporting device of Claim 1, wherein each of the wavy strips connects a concave portion of one of curved segments to a convex portion of another one of the curved segments.

8. The tissue supporting device of Claim 7, wherein only every other one of the curved segments at one end of the first tubular section is connected to one of the wavy strips.

9. The tissue supporting device of Claim 1, wherein each of the wavy strips includes a first portion inclined in a first direction with respect to the aligned segments, a second portion inclined in the first direction, and a third portion inclined in a second direction, the third portion interconnecting the first and second portions and forming acute angles with the first and second portions.

10. The tissue supporting device of Claim 9, wherein the wavy strips interconnect all of the curved segments at one end of the first tubular section with all of the curved segments at one end of the second tubular section.

11. The tissue supporting device of Claim 1, wherein the wavy strips interconnect only some of the curved segments at one end of the first tubular section with only some of the curved segments at one end of the second tubular section.

12. The tissue supporting device of Claim 1, wherein the tissue supporting device is expandable from a first configuration to a second configuration, the second configuration having a pattern of only identically shaped expanded openings.

13. The tissue supporting device of Claim 1, wherein the tissue supporting device is expandable from a first configuration in which the aligned segments abut each other to a second configuration in which the aligned segments form a ring of wishbone-shaped segments.

14. The tissue supporting device of Claim 1, wherein the tissue supporting device is expandable from a first configuration in which the wavy strips abut each other to a second configuration in which the wavy strips are spread apart in a circumferential direction and maintain substantially the same shape as in the first configuration.

15. The tissue supporting device of Claim 1, wherein the tissue supporting device includes a third tubular section interconnected to the second tubular section by a second bridging section.

16. The tissue supporting device of Claim 15, wherein the tissue supporting device includes a fourth tubular section interconnected to the third tubular section by a third bridging section.

17. The tissue supporting device of Claim 16, wherein the tissue supporting device includes a fifth tubular section interconnected to the fourth tubular section by a fourth bridging section.

18. The tissue supporting device of Claim 17, wherein the tissue supporting device includes a sixth tubular section interconnected to the fifth tubular section by a fifth bridging section.

19. The tissue supporting device of Claim 18, wherein the tissue supporting device includes a seventh tubular section interconnected to the sixth tubular section by a sixth bridging section.

20. The tissue supporting device of Claim 1, wherein some of the curved segments are enlarged curved segments which define a series of teardrop-shaped openings at opposite ends of the first and second tubular sections.

21. The tissue supporting device of Claim 20, wherein each of the enlarged curved segments abuts another one of the enlarged curved segments.

22. The tissue supporting device of Claim 1, the tubular and bridging sections being comprised of a unitary piece of a shape-memory alloy which transforms from a martensitic metallurgical state to an austenitic metallurgical state when heated above a first transition temperature A_f and transforms from the austenitic state to the martensitic state when cooled below a second transition temperature M_f, the tissue supporting device being mechanically deformable without plastic deformation in a body passage of a living person from a first configuration while in the martensitic state to a second configuration in the martensitic state and the A_f temperature being sufficiently above a body temperature of the living person to prevent recovery of the tissue supporting device to the first configuration by heating the tissue supporting device above A_f without permanently damaging surrounding tissue of the living person, the tissue supporting device exhibiting a strain on a plateau of a stress-strain curve of the shape-memory alloy when permanently positioned in the body passage.

23. The tissue supporting device of Claim 1, wherein the first tubular section, the second tubular section and the wavy strips comprise an etched, electric discharge machined or laser-cut tube or sheet of metal.

24. The tissue supporting device of Claim 23, wherein the metal is selected from the group consisting of stainless steel, nickel-titanium, shape memory alloy, tantalum, gold, and biocompatible metallic material.

25. The tissue supporting device of Claim 22, wherein the shape-memory alloy is an alloy of Ni and Ti having radiopacity and/or $A_f \geq 62°C$ and/or the tissue supporting device includes a coating providing a surface finish which minimizes thrombosis.

26. The tissue supporting device of Claim 1, wherein the curved segments at one end of each of the aligned segments is connected to the curved segment of an adjacent one of the aligned segments by a portion of one of the bridging members, each of the bridging members comprising a continuous wavy strip extending the entire length of the tissue supporting device.

27. A flexible tissue supporting device comprising:

a first tubular section and a second tubular section interconnected by a bridging section, each of the tubular sections including aligned segments and curved segments, each of the aligned segments being connected to an adjacent one of the aligned segments by only one of the curved segments, the bridging section comprising a plurality of wavy strips, each of the wavy strips being connected between one of the curved segments of the first tubular section and one of the curved segments of the second tubular section, each of the wavy strips including a first portion inclined in a first direction, a second portion inclined in the first direction, and a third portion inclined in a second direction, the third portion interconnecting the first and second portions and forming acute angles with the first and second portions.

28. A flexible tissue supporting device comprising a first tubular section and a second tubular section interconnected by a bridging section, each of the first and second tubular sections comprising a continuous strip having aligned segments and curved segments, each of the curved segments interconnecting adjacent ends of a pair of the aligned segments, the tissue supporting device being expandable from a first configuration in which the aligned segments abut each other to a second configuration in which the aligned segments form a ring of wishbone-shaped segments.

29. A flexible tissue supporting device comprising a first tubular section and a second tubular section interconnected by a bridging section, each of the first and second tubular sections comprising a continuous strip having aligned segments and curved segments, each of the curved segments interconnecting adjacent ends of a

pair of the aligned segments, some of the curved segments being enlarged curved segments which define a series of teardrop-shaped openings at opposite ends of the first and second tubular sections.

30. A flexible tissue supporting device comprising a first tubular section and a second tubular section interconnected by a bridging section, each of the tubular sections including aligned segments and curved segments, the bridging section comprising a plurality of wavy strips, the tubular and bridging sections being comprised of a unitary piece of a shape-memory alloy which transforms from a martensitic metallurgical state to an austenitic metallurgical state when heated above a first transition temperature A_f and transforms from the austenitic state to the martensitic state when cooled below a second transition temperature M_f, the tissue supporting device being mechanically deformable without plastic deformation in a body passage of a living person from a first configuration while in the martensitic state to a second configuration in the martensitic state and the A_f temperature being sufficiently above a body temperature of the living person to prevent recovery of the tissue supporting device to the first configuration by heating the tissue supporting device above A_f without permanently damaging surrounding tissue of the living person, the tissue supporting device exhibiting a strain on a plateau of a stress-strain curve of the shape-memory alloy when permanently positioned in the body passage.

31. A tubular tissue supporting device comprising a plurality of circumferentially spaced apart wavy strips, each of the wavy strips being continuous and extending axially along the entire length of the tissue supporting device, each of the wavy strips being connected to an adjacent one of the wavy strips by expandable members.

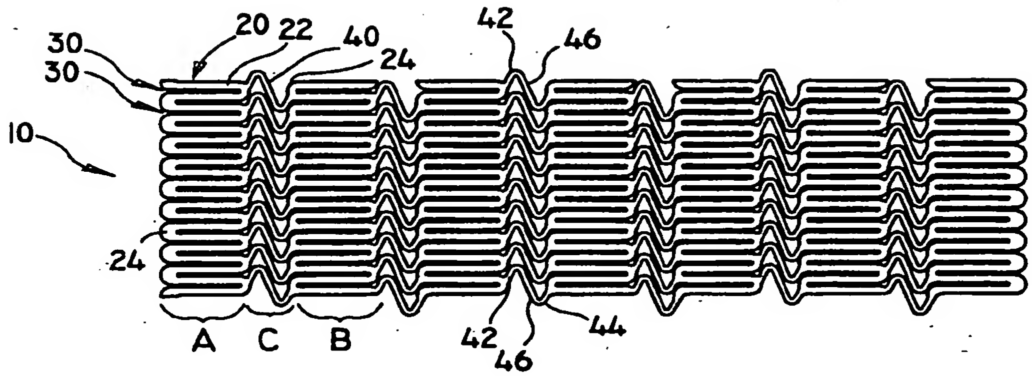


FIG. 1

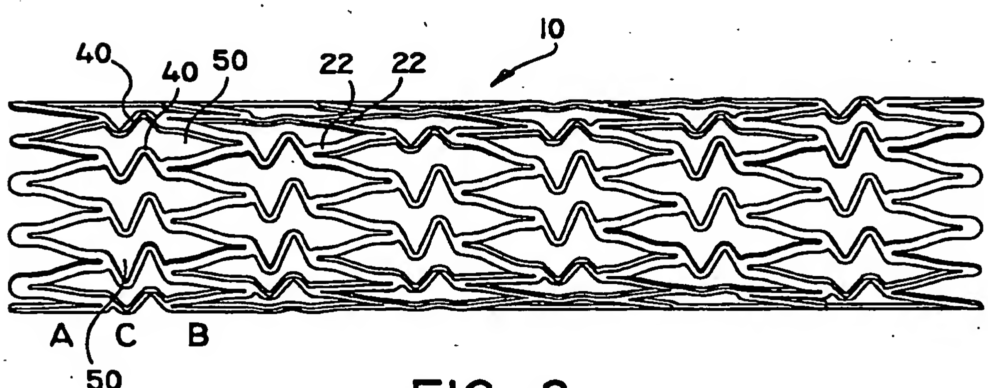


FIG. 2

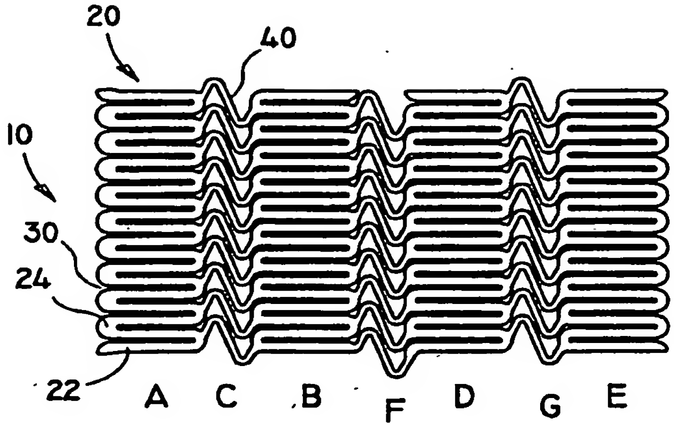


FIG. 3

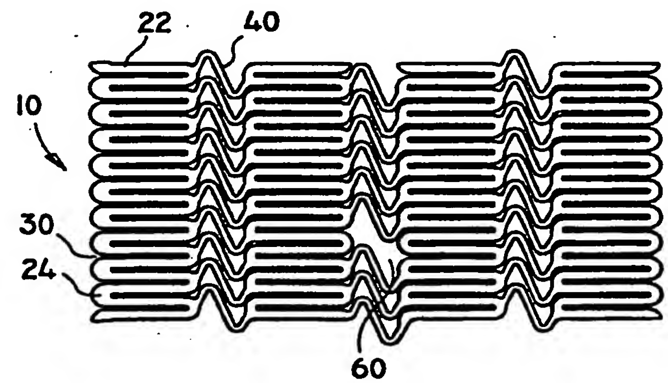


FIG. 4

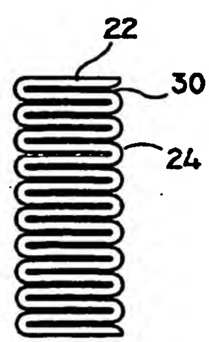
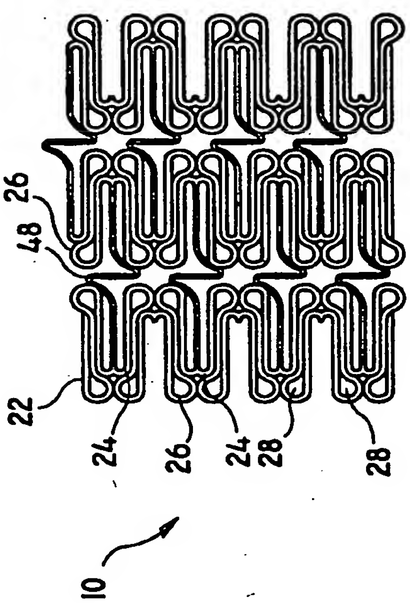
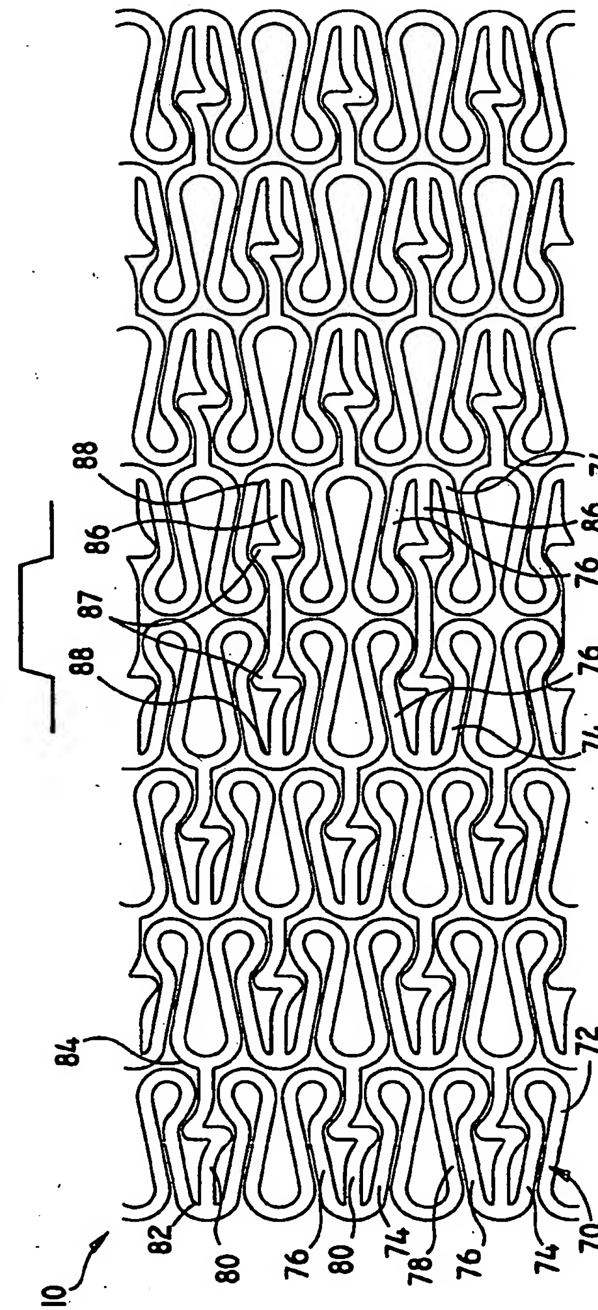


FIG. 5



10
22
24
26
24
28
28
26
48
A
B

FIG. 6



10
82
80
76
80
74
78
76
74
70
72
84
88
86
87
88
74
86
76
76
74

FIG. 7

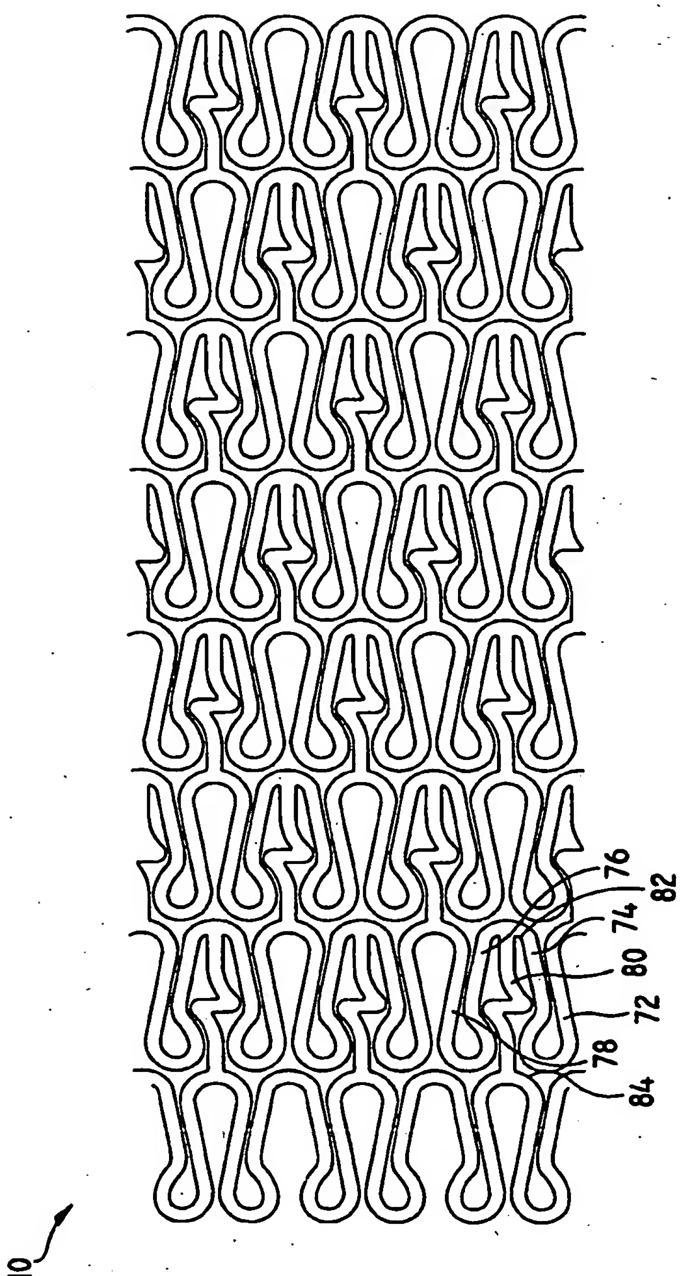


FIG. 8

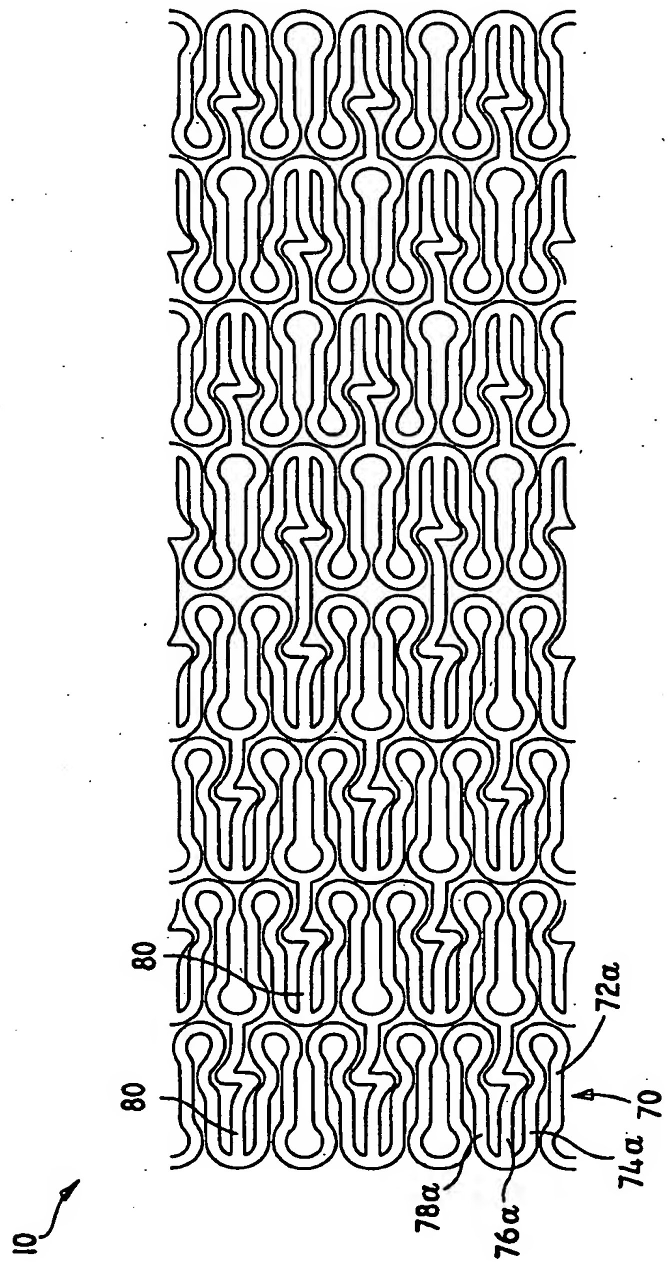


FIG. 9

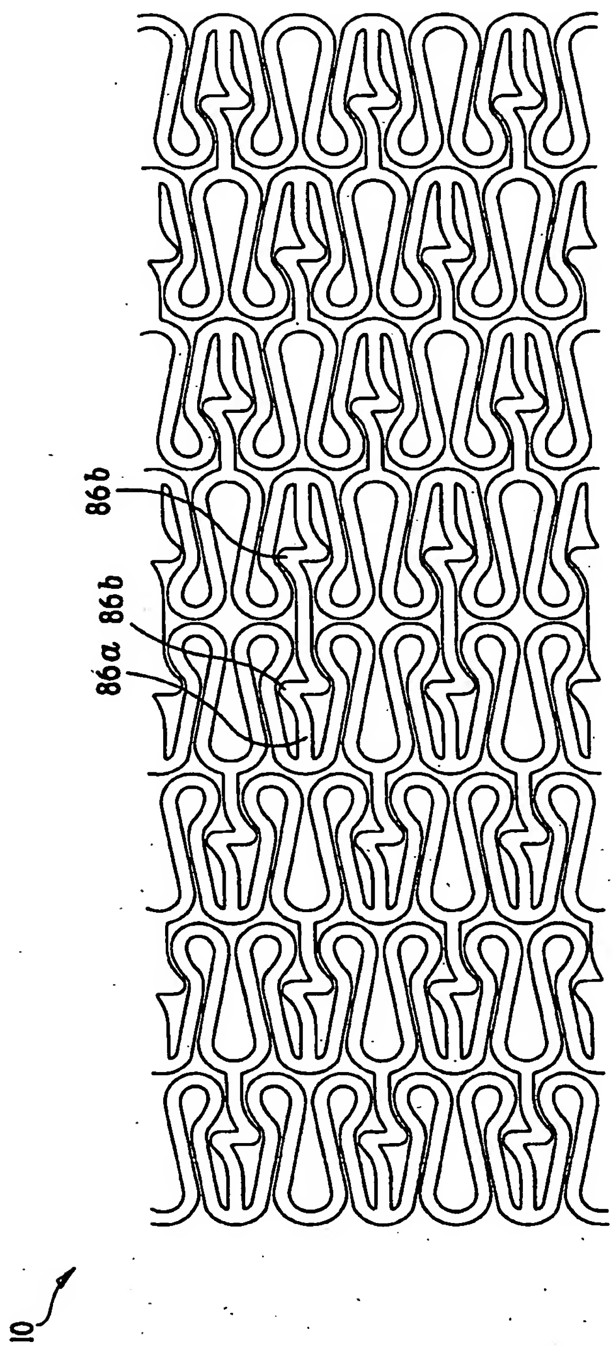


FIG. 10

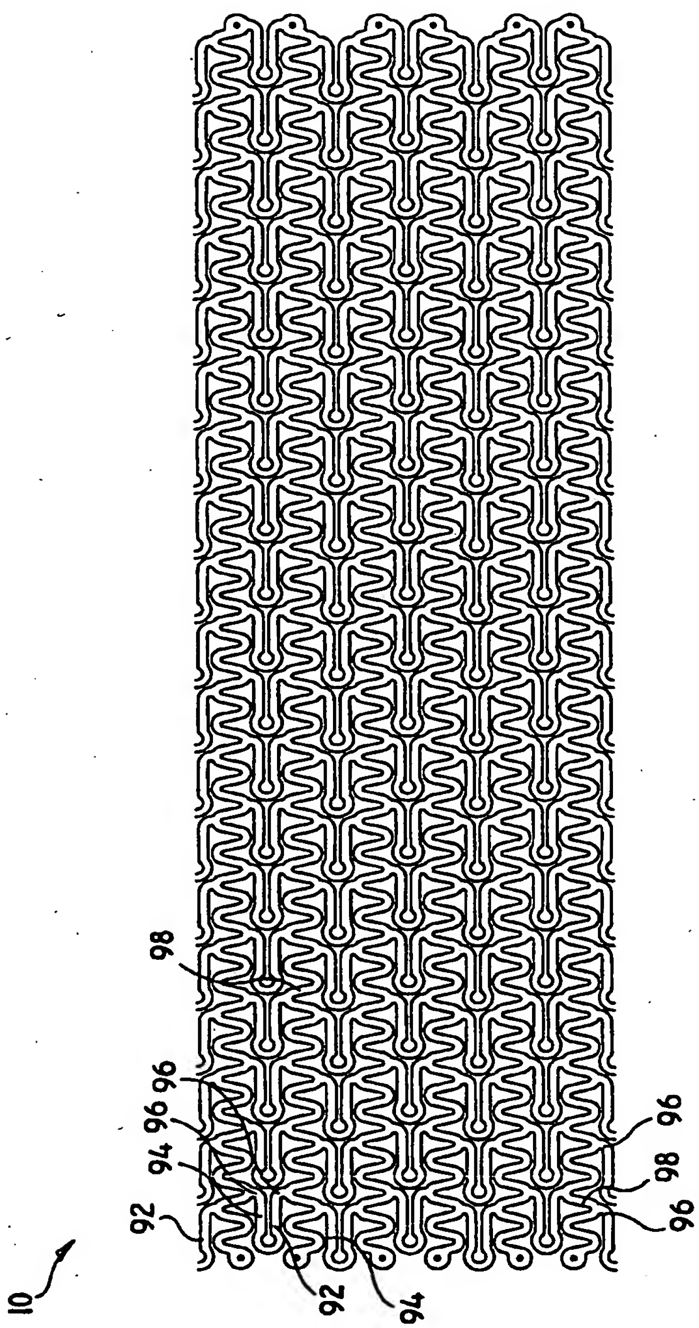


FIG. 11

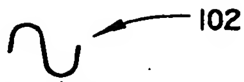


FIG. 12A

FIG. 12B

FIG. 12C

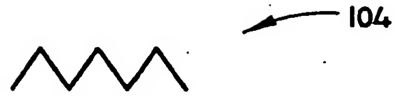


FIG. 12D

FIG. 12E

FIG. 12F

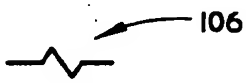


FIG. 12G

FIG. 12H

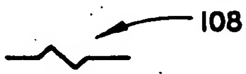


FIG. 12I

FIG. 12J

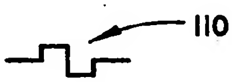


FIG. 12K

FIG. 12L

FIG. 12M

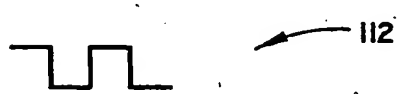


FIG. 12N

FIG. 12O

FIG. 12P

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/05014

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/06
US CL :606/192, 194, 195, 198; 623/1, 11, 12
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/192, 194 195, 198; 623/1, 11, 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,E	US 5,733,303 A (ISRAEL et al) 31 March 1998, entire reference, and Figs. 7 and 8.	1-8, 11-17, 20, 21, 23, 24, 26, 28, 29, 31
Y	US 5,449,373 A (PINCHASIK et al) 12 September 1995, Fig. 3C.	9, 10, 18, 19, 27
Y	US 5,562,922 A (LAMBERT) 08 October 1996, entire reference.	22, 25, 30

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search 20 JULY 1998	Date of mailing of the international search report 19 AUG 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JOHN M. BLACK Telephone No. (703) 305-7341

Form PCT/ISA/210 (second sheet)(July 1992)★